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NATERA, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA,

SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.

Plaintiff and Counterclaim-Defendant,

vs.

NATERA, INC.

Defendant and Counterclaim-Plaintiff.

CASE NO. 3:21-CV-04062-EMC

NATERA, INC'S REQUEST FOR LEAVE TO FILE A MOTION FOR RECONSIDERATION

FILED UNDER SEAL

Pursuant to Local Rule 7-9(a), Natera respectfully seeks leave to request reconsideration of portions the Court's Orders of (1) March 6, 2024 (Dkt. 493) ("COBRA Order") and (2) March 22, 2023 (Dkt. 326) ("SJ Order") based upon recent revelation of material evidence. As part of COBRA discovery, third party NRG Oncology ("NRG") produced documents on July 9, 2024 and August 15, 2024 that show Guardant knew its "CHIP filter" did not work as claimed in Guardant's Complaint: it did not prevent false positive results from non-cancerous CHIP mutations, and was thus unable to filter out biological noise—exactly as Natera had stated in 2021.

INTRODUCTION

Clonal hematopoiesis is an aging-related phenomenon in which blood cell DNA spontaneously mutates. It is referred to as "CHIP." A risk for blood assays that seek to detect the return of colorectal cancer is that biological noise such as CHIP mutations may be flagged as tumor DNA, leading to "false positives." In 2021, Natera published a White Paper describing the differences between tumor-informed and tumor-naïve assays in which it made the following statements: "Specificity is impacted by biological noise from germline and CHIP mutations" and "[w]ithout the genomic information for each primary tumor, tumor-naïve assays are unable to filter out background biological noise from CHIP …."

Guardant accused this statement of being literally false under the Lanham Act specifically because Guardant's tumor-naïve assay included software called a "CHIP filter" designed to detect CHIP mutations, leading to—according to Guardant in its complaint—100% specificity. An assay with 100% specificity means no false positives. This Court issued a summary judgment order regarding "Reveal's CHIP filter capabilities" and ruled there was a genuine issue for trial as to "how well [Reveal's CHIP filter] worked." Dkt. 326 at 26.

As this Court knows, NRG—sponsors of the COBRA trial—terminated the trial based on its interim results. The sponsors informed doctors that the termination was due to higher-than-expected rates of false positives. COBRA used Guardant's Reveal assay. In seeking to ***exclude*** COBRA from trial, Guardant's counsel filed a letter asserting that the COBRA results had nothing to do with its assay's "CHIP filter." Dkt. 484. On March 6, 2024, this Court—apparently relying on counsel's representations and the lack of documents to the contrary—ruled that "the COBRA study does not

bear on whether Reveal uses a CHIP filter or whether the CHIP filter improves Reveal's specificity or sensitivity." Dkt. 493 at 10.

On July 9, 2024 and August 15, 2024, however, NRG produced documents demonstrating that Guardant misled Natera and this Court. The documents disclosed that in [redacted] Guardant never provided [redacted] to Natera, but in connection with the COBRA trial provided it to NRG—which produced it to Natera. Guardant also told NRG that [redacted]—not 100% as set forth in the complaint. Furthermore, in an effort explain the poor interim results from its assay and persuade the NRG to continue the COBRA trial, Guardant [redacted] Guardant addressed specificity with NRG because of the apparent false positives in the COBRA study.

This information is material to this Court's orders on specificity and COBRA. Indeed, the new facts render the Court's decisions on CHIP incorrect. These specificity revelations should have been disclosed by Guardant long before. Guardant was prepared to go to trial in November of 2023 and March of 2024 as if its assay had 100% specificity and its CHIP filter was unchanged, and as if false positives were not a central issue to the COBRA termination. None of that was true. Guardant [redacted] exactly because of false positives from CHIP mutations, and told NRG that fact—but not Natera or this Court. Natera requests leave to file for reconsideration so that it can address this newly discovered information.

BACKGROUND

On May 3, 2021, Natera issued a technical paper comparing tumor-informed and tumor-naïve approaches for early-stage molecular residual disease ("MRD") detection ("White Paper"). Ex. 1 (Trial Ex. 120, NATER_350767). The White Paper, which did not mention Guardant Reveal by name, included the following statement about the impact of biological noise, such as CHIP, on assay specificity:

- **Specificity is impacted by biological noise from germline and CHIP mutations.** Without the genomic information for each primary tumor, tumor-naive assays are unable to filter out background biological noise from CHIP or to avoid tracking driver mutations that may be subjected to selection pressure from treatment.

On May 27, 2021, Guardant filed its false advertising complaint. Dkt. 1. Guardant asserted that the White Paper statement was "false" because Reveal has bioinformatic software and its specificity is 100% as a result of the "CHIP filter":

> But this is false; Reveal can and does filter out CHIP background noise bioinformatically. In fact, data publicly presented in 2018 on a prototype of the Reveal assay showed 100% specificity with incorporation of the CHIP filter.

Id. at ¶ 32.

Throughout discovery, Guardant maintained that no updates were made to the commercial Reveal assay. Natera's Interrogatory No. 14 requested that Guardant "[i]dentify all versions of the genomic and/or epigenomic calling pipeline(s) and/or algorithm(s) ever used as part of Reveal." Ex. 2 (Guardant 4/8/22 Response to Rog No. 14). In response, Guardant stated:

[redacted]

Id. at 19 (emphasis added). Guardant never updated its response.

On October 14, 2022, Natera filed for summary judgment relating to Guardant's Lanham Act claims, including the literal falsity of the White Paper claims directed to CHIP mutations. Dkt.

220. The Court denied Natera's motion with respect to "Reveal's CHIP filter capabilities" stating:

> ***"There remains a genuine dispute of material [fact] as to whether Guardant's CHIP filter existed and how well it worked."***

Dkt. 326 at 26. On June 8, 2023, Guardant filed its pretrial conference statement reiterating the summary judgment decision about CHIP filters as an issue for trial—then scheduled for November 2023. Dkt. 366-4 at 6-7.

On January 31, 2024, Natera served the supplemental expert report of oncologist Dr. Howard Hochster, prompting Guardant to file a motion to strike. Dkt. 447-2. Dr. Hochster's supplemental report addressed the COBRA trial termination, the public presentation of those results at a conference on January 20, 2024, and Dr. Hochster's opinion that the COBRA termination confirmed his opinion that tumor-naïve assays like Reveal were more prone to false positives. *Id*.

NRG's August 30, 2023 letter to doctors whose patients were enrolled in COBRA stated that the reason for the study's closure was false positives from the Reveal assay:

> We have been informed by our diagnostic partner that a greater than anticipated number of participants may have been 'false positives", i.e., designated ctDNA+ incorrectly. While this was a recognized potential risk of the study, this rate is higher than we had expected. Thus, a subset of COBRA patients randomized to Group 2 who tested positive for ctDNA received chemotherapy based on what is potentially a "false positive" result. ***The higher-than-expected "false positive" rate resulted in the trial not passing the interim analysis and, as such, the trial will be closed to accrual.***

Dkt. 447-2 at Hochster Exhibit 7 (emphasis added). In real world terms, this means some patients may have received unnecessary chemotherapy based on "false positive" results from Guardant's Reveal assay.

Guardant sought to exclude COBRA from trial in this case then scheduled for March 11, 2024. Guardant's counsel argued that COBRA was "irrelevant to any remaining claim in this false advertising case." Dkt. 447 at 4. During the COBRA hearing, Guardant feigned ignorance as to the details of the COBRA trial and claimed that it would need extensive discovery related to COBRA because "[COBRA] is not a published study, and the data that's typically available that would allow [Guardant] to respond, allow [Guardant] to analyze the underlying data, ***is not currently available to Guardant***." Ex. 3 (Feb. 21, 2024 Hr'g Tr.) at 5:7-11. That was false.

On March 1, 2024, in an effort to exclude COBRA, Guardant's counsel filed a letter with explicit representations that COBRA was irrelevant to any CHIP filter issue in the case. Dkt. 484. Counsel referred to the SJ Order as "law of this case" and represented to the Court that the "[i]nterim data from COBRA in 2023 will not make the answer to the factual question at issue [for trial] more or less likely to be true." Dkt. 484 at 3-4; *id*. at 3 (quoting Dkt. 326 (SJ Order – "whether Guardant's CHIP filter existed and how well it worked").

On March 6, 2024, this Court issued an order permitting limited discovery relating to the COBRA trial. Dkt. 493. However, in relying on Guardant's representations to the Court regarding its CHIP filter, the Court stated that "the COBRA study does not bear on whether Reveal uses a CHIP filter or whether the CHIP filter improves Reveal's specificity or sensitivity. Thus, the COBRA study is irrelevant to Natera's defense against Guardant's specific challenge and is not admissible for this purpose." *Id*. at 10. As a result of the COBRA discovery, the Court ultimately set the trial date for November 12, 2024. Dkt. 471; Dkt. 501; Dkt. 557.

COBRA discovery from NRG has fundamentally altered this case—specifically with respect to the capabilities of Guardant's "CHIP filter" software, and its assertion in its complaint of 100% specificity. The following documents are exemplary:

May 30, 2023 [redacted] ***(Ex. 4)***. NRG produced this document on August 15, 2024. It is [redacted]

Guardant never disclosed to Natera that it [redacted] Indeed, Guardant seeks damages beyond January 2023 and maintains that the sales of the new version of the assay is germane to the amount of corrective advertising to which it is entitled. Dkt. 603 at 1-2.

June 22, 2023 Email to NRG Oncology (Ex. 5). After Natera issued a subpoena to NRG, Guardant produced this document on June 5, 2024, and NRG subsequently produced this same document on July 9, 2024. It is an email from a Guardant scientific officer to NRG concerning the

interim COBRA results. It notes that [redacted] *Id.* The email goes on, [redacted] *Id.*

In addition, [redacted] *Id.* ([redacted]) (emphasis added). [redacted] *Id.*; *see also* Ex. 6 (NRG-000087) ([redacted]).

July 26, 2023 Letter to NRG Oncology (Ex. 7). NRG produced this document on July 9, 2024. This formal letter from Guardant to NRG includes a [redacted] and warns that NRG must keep the correspondence confidential. The letter reveals that the [redacted] was verified on January 25, 2023 and [redacted] of the assay. Ex. 7 at 2. The attached report discloses that [redacted] *Id.* at 3. The report further discloses that [redacted] *Id.* at 4.

Guardant's Chief Medical Officer confirmed at deposition [redacted] Ex. 8 (Eagle Tr.) 153:23-154:3, 154:11-20.

The NRG documents also revealed that Guardant [redacted] (Ex. 9 (NRG-N-001369) at -1370), [redacted] (Ex. 5 (GHI00063336)), and [redacted] (Ex. 10 (GHI00063364)).

LEGAL STANDARD

A party must obtain leave to file a motion for reconsideration. Civil L.R. 7-9(a). Such a motion is appropriate when brought with reasonable diligence and, as applicable here: (1) that at the time of the motion for leave, a material difference in fact or law exists from that which was presented to the Court before entry of the interlocutory order for which reconsideration is sought. The party also must show that in the exercise of reasonable diligence the party applying for reconsideration did not know such fact or law at the time of the interlocutory order; or (2) the emergence of new material facts or a change of law occurring after the time of such order. Civil L.R. 7-9(a).

LEAVE FOR RECONSIDERATION IS WARRANTED

I. NEW MATERIAL FACTS HAVE EMERGED WARRANTING RECONSIDERATION OF THE COURT'S PRIOR ORDERS

It is a material fact to the Court's March 6, 2024 COBRA Order that when COBRA interim results came in with "higher than expected false positives," Guardant told NRG that [redacted] Ex. 5. Indeed, Guardant shared its [redacted] that showed Guardant [redacted] Ex. 4 This information directly contradicts the Court's conclusion, based on Guardant's representations, that "the COBRA study does not bear on whether Reveal uses a CHIP filter or whether the CHIP filter improves Reveal's specificity or sensitivity." Dkt. 493 at 10.

The true facts—which Natera only learned after the Court's order and which Guardant was apparently never going to disclose—demonstrate that [redacted] As such, the new facts warrant a reconsideration of the Court's conclusion. Natera should be given the opportunity to show the jury these facts and why COBRA is relevant to the CHIP filter issue.

Furthermore, the new facts are material to the SJ Order and demonstrate the conclusion was incorrect. The issue for trial, based on Natera's actual statement in its White Paper, is not a binary question of whether Guardant labeled some part of its software a "CHIP Filter." The issue—as set

forth in the SJ Order—encompasses the "capabilities" of an alleged CHIP Filter, as well as "how well it worked"—*i.e.*, does it actually prevent false positives from CHIP mutations. Dkt. 326 at 26. Indeed, as set forth in the Complaint, Guardant's litigation position turns on whether the CHIP filter had 100% performance or not.

In its Complaint (reaffirmed in its final pretrial statement) Guardant linked Natera's CHIP filter statements to Guardant's position that studies show Reveal has "100% specificity." Dkt. 1 ¶ 32. That is, that Reveal has no false positive results. But the newly uncovered COBRA documents show Reveal does ***not*** have 100% specificity and never did. Guardant told NRG [redacted] Ex. 7 (NRG-000122) at -124, -127. Guardant's complaint alleging falsity of Natera's statement regarding tumor-naïve assays being unable to filter out biological noise was incorrect. Guardant conceded that [redacted]—exactly the position set forth in Natera's White Paper.

The relevance to the SJ Order is underscored by the high standard for literal falsity under the Lanham Act. Guardant may argue that Natera implied or stated that Reveal has no CHIP filter whatsoever. That misconstrues what Natera said. First, Natera said that specificity is impacted by biological noise. Second, Natera said that tumor-naïve assays are unable to filter out biological noise. The first statement is undisputed; the second has turned out to be true. To the extent there is any ambiguity in Natera's statements, that does not meet the test for literal falsity. To be literally false, only unambiguous messages that are demonstrably true or false can be the basis of Lanham Act liability. *Design Res., Inc. v. Leather Indus. of Am.*, 789 F.3d 495, 501-03 (4th Cir. 2015) (citing *Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002)). Natera's moderate statements within a technical paper pointing out that tumor-naïve tests have an issue identifying CHIP mutations have been fully confirmed by the COBRA NRG documents as well as Guardant's [redacted].

There is no longer any genuine issue as to whether Reveal had 100% specificity in 2021; Guardant told [redacted] It cannot be literally false advertising

for Natera to point out in a technical paper that tumor-naïve assays have issues filtering out CHIP mutations and that biological noise affects specificity. Natera therefore requests leave to renew its motion for summary judgment on the CHIP filter issue in light of the newly uncovered facts.

II. NATERA EXERCISED REASONABLE DILIGENCE

Guardant both neglected to produce relevant information and also affirmatively misrepresented the significance of COBRA. As such, Natera had no way to learn of the new facts until NRG—a third party—produced its communications with Guardant about its assay results, and Guardant's [redacted]

It was Guardant's obligation to update its interrogatory answer about its software. And it was Guardant's obligation to produce documents in this case when it was secretly sending material information to NRG as part of the COBRA trial. There was no way for Natera to know these documents existed. Indeed, Guardant insisted that NRG must keep confidential [redacted] Ex. 7 (July 26, 2023 letter stating Guardant's [redacted] information is [redacted]). And Guardant's counsel wrote to the Court to assert—falsely—that there was nothing in the COBRA study that bore upon issues related to the existence and performance of the CHIP filter. Dkt. 484. Indeed, in Court hearings, Guardant feigned ignorance about COBRA when in reality newly produced documents show it was closely involved, including [redacted]. Ex. 9 (NRG-N-001369); Ex. 5 (GHI00063336); Ex. 10 (GHI00063364).

NRG produced the key documents in July and August 2024. Ex. 11. In bringing this motion, Natera has moved with reasonable diligence. Indeed, any delay is the fault of Guardant for not producing the documents itself.

III. GUARDANT'S MISCONDUCT FURTHER SUPPORTS RECONSIDERATION OF THE COURT'S PRIOR ORDERS

Guardant knew [redacted] in ways material to the issues in this case, and yet sat silent. To explain the poor interim study results, Guardant admitted (in secret) to NRG that [redacted]—and 100% specificity is the reason Natera's

statements about CHIP mutations are allegedly false. Guardant [redacted] —and yet never told Natera or this Court. These are significant acts of misconduct that if not discovered would have led to a trial based on false facts. This is compounded by Guardant's written assertions to this Court that COBRA was unrelated to CHIP filter issues.

It is fundamentally unfair for Guardant to be able to obtain favorable rulings on COBRA and its CHIP Filter while withholding critical information. *Pumphrey v. K.W. Thompson Tool Co.*, 62 F.3d 1128, 1133 (9th Cir. 1995) (finding that defendant "undermined the judicial process" through failure to disclose evidence, affirmatively mischaracterizing evidence relating to certain test results, and letting stand uncorrected "the false impression created by" the witness who performed the tests); *Hernandez v. Results Staffing, Inc.*, 907 F.3d 354, 358-59, 365-66 (5th Cir. 2018) (relief from judgment appropriate after the defendant discovered the plaintiff failed to disclose medical records indicating the plaintiff visited an emergency room primarily because of a headache, rather than a pre-existing back injury as the plaintiff alleged); *Canady v. Erbe*, 99 F. Supp. 2d 37, 49 (D.D.C. 2000) (setting aside summary judgment in a patent action because party failed to disclose "clearly responsive, relevant and non-privileged documents"); *Cap Export, LLC v. Zinus, Inc.*, 996 F.3d 1332, 1338-42 (Fed. Cir. 2021) (affirming district court's decision because "Lawrie, Zinus's president and expert witness, misrepresented his knowledge of highly material prior art," this court "properly declined to condone such conduct"). As such, Natera should be permitted to seek reconsideration of both the COBRA order as it relates to CHIP as well as the SJ Order.

CONCLUSION

Natera respectfully requests the Court grant the relief requested herein.

DATED: August 26, 2024

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